Notice of Allowability	Application No.	Applicant(s)	
	09/719,316	SHIMIZU, YASUHIKO	
	Examiner	Art Unit	
	Jennifer A. Boyd	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *12/12/05*.

2. ☒ The allowed claim(s) is/are *1-3,5 and 8-28*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *01/05/06* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Response to Amendment

1. The Applicant's Amendments and Accompanying Remarks, filed December 12, 2005, have been entered and have been carefully considered. All rejections have been overcome.

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Russett on 1/4/06.

9. (Currently amended) ~~(Previously Presented)~~ The collagen material according to claim 2, where said collagen material has one-point support tensile force of at least 30 N and rupture resistance tensile force of at least 65 N in the dry state, and has one-point support tensile force of at least 1.4 N and rupture resistance tensile force of at least 6.5 N in the wet state [[(]] for a thickness of 1 mm [[)]].

10. (Currently amended) ~~(Previously Presented)~~ The collagen material according to any one of claims 3, 5 or 8, wherein said collagen material has one-point support tensile force of at least 10 N and rupture resistance tensile force of at least 25 N in the dry state, and has one-point support

tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state [[(]] for a thickness of 1 mm [[)]].

11. (Currently amended) ~~(Withdrawn - Currently Amended) A production process of~~ A process for producing the collagen material according to claim 1, comprising performing at least the steps indicated below in order:

a. collagen solution layer is formed by casting a hydrochloric acid solution of extracted collagen to a desired thickness;

b. said collagen solution layer is temporarily frozen and held in that static for a desired amount of time followed by freeze-drying;

c. thermal dehydration crosslinking is performed for a predetermined amount of time on said freeze-dried product;

d. said hydrochloric acid solution of extracted collagen is introduced into the matrix of said thermal dehydration crosslinked product;

e. the product introduced said solution of extracted collagen therein is temporarily frozen, held in that state for a predetermined amount of time and then freeze-dried;

g. said freeze-dried product is compressed; and,

i. thermal dehydration crosslinking is performed for a predetermined amount of time on that compressed product.

12. (Original) ~~(Withdrawn)~~ The process according to claim 11, wherein the following steps are performed in order between said step e and step g:

f1. said hydrochloric acid solution of extracted collagen is again introduced in the matrix of said freeze-dried product; and,

f2. the product introduced said extracted collagen solution therein is temporarily frozen, held in that state for a desired amount of time, and then freeze-dried.

13. (Previously presented) ~~(Withdrawn—Currently amended)~~ The process according to claim 11 or 12, wherein the following step is performed between said steps g and i:

h1. a collagen solution layer is formed at a predetermined site on the surface of said compressed product.

14. (Original) ~~(Withdrawn)~~ The process according to claim 13, wherein the following step is performed between said steps h1 and i:

h2. said collagen solution layer is compressed.

15. (Previously presented) ~~(Withdrawn—Currently amended)~~ The process according to claim 11 or 12, wherein the freezing and holding time during the freezing procedure in said steps b, e and f2 is 6-48 hours.

16. (Previously presented) ~~(Withdrawn—Currently amended)~~ The process according to claim 11 or 12, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen in said steps d and f1 is 0.5 wt% or less.

17. (Previously presented) ~~(Withdrawn—Currently amended)~~ The process according to claim 13, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen for forming a collagen solution layer in said step h1 is 2.0 wt% or less.

18. (Previously presented) ~~(Withdrawn—Currently amended)~~ The process according to claim 11 or 15, wherein casting of a hydrochloric acid solution of extracted collagen in said step a is divided into two procedures, and a mesh-like sheet or tube comprising a material selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate and a mixture of polyglycolic acid and polylactic acid is contained between both collagen solution layers between both casting procedures, said step g is performed after said step c while said step i is not performed.

19. (Original) ~~(Withdrawn)~~ The process according to claim 18, wherein the following steps are additionally performed after said step g:

h3. a collagen solution layer or gelatin gel layer is formed on at least one side of said compressed product; and,

h4. thermal dehydration crosslinking is performed on the product formed said collagen solution layer or said gelatin gel layer.

20. (Original) ~~(Withdrawn)~~ The process according to claim 19, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen for forming said collagen solution layer is 2 wt% or less.

21. (Original) ~~(Withdrawn)~~ The process according to claim 19, wherein said gelatin concentration of the gelatin aqueous solution for forming said gelatin gel layer is 5-25 wt%.

22. (Currently amended) ~~(Withdrawn - Currently Amended) A production process of~~ The process of producing the collagen material according to claim 1, comprising performing at least the following steps in order:

j. a hydrochloric acid solution of extracted collagen is introduced into a non-woven fabric-like sheet-like or tube-like matrix comprising a material selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate and a mixture of polyglycolic acid and polylactic acid, followed by air-drying;

l. a collagen solution layer is formed on at least one side of the product introduced and air-dried said hydrochloric acid solution of extracted collagen;

o. a gelatin layer is formed on said collagen solution layer; and,

p. thermal dehydration crosslinking is performed on the product formed said gelatin layer for predetermined amount of time.

23. (Original) ~~(Withdrawn)~~ The process according to claim 22, wherein the following step k is performed between said steps j and 1, and the following step m is performed between said steps 1 and o:

k. the product introduced said extracted collagen is temporarily frozen, and that state is maintained for a predetermined amount of time followed by freeze-drying;

ml. the product on which said collagen solution layer is formed is temporarily frozen, and that state is maintained for a predetermined amount of time followed by freeze-drying; and,

m2. the product freeze-dried is compressed.

24. (Original) ~~(Withdrawn)~~ The process according to claims 22 or 23, wherein the following step n is performed between said steps 1 and o or between said steps m2 and o:

n. thermal dehydration crosslinking is performed for a predetermined amount of time on the product on which said collagen solution layer is formed or the product freeze-dried.

25. (Previously Presented) ~~(Withdrawn—Currently amended)~~ The process according to claim 22 or 23, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen in said steps j and 1 is 2.0 wt% or less.

26. (Previously Presented) ~~(Withdrawn—Currently amended)~~ The process according to claim 22 or 23, wherein the gelatin concentration of the gelatin aqueous solution in said step o is 5-25 wt%.

27. (Currently amended) ~~(Withdrawn - Currently Amended)~~ The process according to claim 11 or 12, wherein the collagen material produced has one-point support tensile force of at least 30 N and rupture resistance tensile force of at least 65 N in the dry state, and one-point support tensile force of at least 1.4 N and rupture resistance tensile force of at least 6.5 N in the wet state [[(]] for a thickness of 1 mm [[)]].

28. (Currently amended) ~~(Withdrawn - Currently Amended)~~ The process according to claim 18, wherein the collagen material produced has one-point support tensile force of at least 10 N and rupture resistance tensile force of at least 25 N in the dry state, and one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 25 N in the wet state [[(]] for a thickness of 1 mm [[)]].

Reasons for Allowance

3. Claims 1 - 3, 5 and 8 – 28 are allowed.

4. The following is an examiner's statement of reasons for allowance: all rejections have been overcome. While Yasuhiko (WO 98/22157) and Bell (US 6,179,872) are considered to be the most pertinent prior art, they fail to teach or suggest a matrix of collagen fibers that are filled with a biocompatible substance and having the claimed fiber structure. It should be noted that the use of the language "consisting of" has excluded the use of the Yasuhiko reference.

Rejoinder of Process Claims

5. Claims 1 – 3, 5 and 8 – 10 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 11 – 28, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a lack of unity requirement, are now subject to being rejoined. Claims 11 – 28 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the lack of unity requirement made in the Office action mailed on September 20, 2002 is hereby withdrawn. It should be noted that claims 11 – 28 are allowed due to their dependency on allowed independent claim 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Boyd
January 5, 2006

ULA RUDDOCK
PRIMARY EXAMINER